

REMARKS

Rejection of the Specification

At page 2 of the office action, the Examiner has objected to the incorporation of allegedly essential material in the specification citing that the specification makes reference to a publication by Morgan et al. (*Biochem. and Biophysical. Research Communication* 225:632-638 (1996)) which recites the sequence of the protein SLIM3 polypeptide.

The publication (at page 633, third paragraph) makes reference to the GenBank accession number U60117 for SLIM3. Therefore, the application properly references where the amino acid sequence for the protein can be easily obtained. Moreover, applicants are not claiming the protein sequence rather a method which utilizes the protein, as admitted by the Examiner at page 3 of the office action. A copy of the Morgan et al. publication is attached. In any event, it is neither necessary or desired to burden an application with essential subject matter, see e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.* (CAFC 1986) 802 F.2d 1367, 231 USPQ 81.

Rejections Under §112, second paragraph

The claims have been rewritten to recite the actual names for the different proteins: androgen receptor(AR), estrogen receptor (ER β) and skeletal muscle LIM-protein 3 (SLIM3). The claims have not been amended for any reason related to patentability and the scope of the claims remains the same.

The term “biologically active derivative” is not vague and indefinite. The specification is replete with disclosure of what is encompassed by such terminology, see e.g., pages 4-6 of the specification.

Rejections Under §112, first paragraph

Claims 1-9 stand rejected under §112, first paragraph for allegedly lacking enablement. Applicants respectfully traverse for the reasons given below.

The enablement rejection is not justified. One of ordinary skill in the art could readily ascertain the possible biologically active derivatives of SLIM3 which have utility in the invention. It is conventional practice in the art to make various derivatives or modifications of a native co-activator protein, e.g., SLIM3, for the purpose of identifying agents which can affect the interaction of the co-activator protein with a target protein, e.g. androgen receptor or estrogen receptor β . The specification is replete with disclosure which adequately serves to guide a skilled worker to carry out the invention without undue experimentation. For example, the various derivatives or modifications can be made with different amino acid substitutions without significantly affecting the function of the protein as determined by assaying the function of the derivative/modification compared to the function of the native protein (specification at page 6, lines 14-21). The modified protein can be assayed by the binding ability and the ability to be a co-factor being tested in SLIM3 (specification at page 7, lines 26-30). The activity of SLIM3 or a derivative thereof can be readily determined using conventional methods in the art and as described in the Examples of the specification at pages 16-19. The Examiner has failed to provide any reasons or evidence why one of skill in the art would not be able to utilize conventional methods in the art to ascertain the biological activity of SLIM3 derivatives/modifications without having to revert to undue experimentation.

Applicants respectfully request that the rejection of the claims under §112, first paragraph is withdrawn.

Prior Art Rejection

Claims 1-9 stand rejected as being anticipated by US 5,789,170 under §102(e). Applicants respectfully traverse.

USP '170 discloses ARA₇₀ which is a co-activator for human androgen receptor in human prostate cells (col.2, lines 10-11). ARA₇₀ is a 614 amino acid protein with a calculated molecular weight of 70 kilodalton (col.2, lines 19-21).

By contrast, applicants method utilizes SLIM3 which is strongly expressed in the myocardium and only weakly expressed in the prostate (specification at page 1, lines 14-16). SLIM3 is a protein of 279 amino acids (specification at page 1, line 13) with a

molecular weight of 31.7kd (Morgan et al. *Biochem. and Biophysical. Research Communication* (1996) 225:632-638).

Clearly, one of ordinary skill in the art would readily recognize that the ARA₇₀ protein disclosed in the '170 patent is not the same protein as SLIM3 nor a biologically active derivative thereof as defined in the present specification. Applicants respectfully request that the rejection of the claims under §102(e) be withdrawn.

In view of the above amendments and remarks, it is submitted that this application is ready for allowance. Early notice to this effect is earnestly solicited. If the Examiner should have any remaining issue(s), he is cordially invited to telephone the undersigned at the number indicated below.

Respectfully submitted,

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